

REMARKS

Entry of the foregoing and favorable reconsideration of the subject application, as amended, pursuant to and consistent with 37 C.F.R. Section 1.112, and in light of the remarks which follow, are respectfully requested.

By the present amendment, Claims 12, 21, 23 and 31 have been amended to respond to the claim objections or to further clarify the present invention. Applicants reserve their rights to file a continuation application directed to the cancelled subject matter. Furthermore, Applicants submit that no new matter has been added via this amendment.

Claim 12 is objected to due since part (b) was previously deleted. This claim has been modified to reflect parts a, b and c only, which should render this objection now moot.

Claim 31 has been objected to under 37 C.F.R. 1.75(c) for failing to further limit the subject matter of a previous claim. Claim 31 has been amended to independent form, which should render this objection now moot.

Claim 23 has been objected to for failure to recite "a field." Claim 23 has been amended to insert "a" in front of field, which should render this objection now moot.

Claims 21 and 33 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. This rejection should now be rendered moot due to the amendment. More specifically, Claim 21 has been amended to delete "at least in one part." Claim 12 has been amended to recite a napine promoter. Support for this amendment appears at least on page 11 of the specification as filed.

In view of the above, withdrawal of this rejection is respectfully requested.

Claims 12 and 33 have been rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a

way as to convey to one skilled in the art, at the time the application was filed, that the inventors had possession of the claimed invention. For the following reasons, this rejection is respectfully traversed.

At least pages 11 and 12 of the specification describe octopine synthase promoter, mannopine promoter, agropine promoter, acyl carrier protein promoter, napine promoter or nopaline promoter. These promoters are well known in the art, as evidenced by the specification, which explains that the structure and cloning of the promoters are known in the literature. Therefore, Applicants submit that it is not necessary to describe what is well known in the art to fulfill the written description requirement, as evidenced by the following Federal Circuit decision:

It is well known in the case law that information that is well known in the art need not be described in the specification. See, *Hybritech, Inc. v. Monoclonal Antibodies, Inc.* 802 F. 2d 1367, 1379-80, 231 USPQ 81, 90 (Fed. Cir. 1986).

See also *Capon v. Eshhar*, 76 USPQ2d 1078, (Fed. Cir. 2005) at page 11 where the Federal Circuit stated the following:

The chimeric genes here at issue are prepared from known DNA sequences of known function. The Board's requirement that these sequences must be analyzed and reported in the specification does not add descriptive substance. The Board erred in holding that the specifications do not meet the written description requirement because they do not reiterate the structure or formula or chemical name for the nucleotide sequences of the claimed invention.

Thus, Applicants submit that the known promoters described in the specification do have to be described by their structure to satisfy the written description requirement as evidenced by the above case law.

Therefore, in view of the above, withdrawal of this rejection is respectfully requested.

Claims 1 and 37 have been rejected under 35 U.S.C. § 102(e) as being anticipated by Schmid (U.S. Patent 5,936,139). For the following reasons, this rejection is respectfully traversed.

Schmid discloses plants that are transformed with a **partial** bacterial cyclopropane acid synthase gene to produce cyclopropane fatty acids having a saturated three-member ring. More specifically, Schmid describes the production of dihydrosterculate, as it is stated at column 1, lines 61 to 66:

Physically **cyclopropane fatty acids** have characteristics between those of saturated and monosaturated fatty acids, and closer to the latter, **while the strained bond angles of the ring give them a unique chemistry**, as described by Christie, W.W. (1970) in *Cyclopropane and Cyclopropane Fatty Acids. Topics in Lipid Chemistry* 1:1-49 (emphasis added).

Cyclopropane fatty acid are not considered branched chain fatty acids as indicated at least on page 3 of the specification where it is stated:

As emerges from the text of the present application, the term "branched" designates in the sense of the invention fatty acids bearing more than one or more substitutions at one or more distinct positions of the aliphatic chain. Thus, the sole presence of a ring in the aliphatic chain is insufficient to qualify the fatty acid as branched according to the invention.

Schmid fails to disclose that branched chain fatty acids were in fact produced from their genetic construct. Indeed, Table 2 of the Schmid patent shows that several palmitic and stearic fatty acids were found in the plants; i.e., unsaturated palmitic acid 16:0 and saturated palmitic acid 16:1. These are not branched chain fatty acids, since in this chemical nomenclature the 1 refers to the number of double bonds.

Indeed, it can be said that Schmid cannot inherently produce branched chain fatty acids since the construct used in this patent was 400 bp shorter than that used in the examples of the present invention. (Compare Figure 4 of the present invention with Wang et al and Schmid, who use the same reduced sequence).

Indeed, the only mention of branched chain fatty acids in Schmid is at column 2, lines 47 to 63, which describes that the branched chain fatty acids can be produced from DHS after hydrogenation. Hydrogenation is a chemical reaction in which unsaturated bonds between carbon atoms are reduced by an attachment of a hydrogen atom to each carbon.

Therefore, Schmid does not teach that they obtained branched chain fatty acids by their cyclopropane synthase construct in plants. Rather the branched chain fatty acids are disclosed in Schmid as being obtained by a chemical process. Therefore, Claims 1 and 37 cannot be anticipated by this patent.

Therefore, in view of the above, withdrawal of this rejection is respectfully requested.

Claims 1, 2, 12, 13, 17, 18, 20, 21, 23, 30, 31, 33 and 37 have been rejected under 35 U.S.C. § 103 (a) as being unpatentable over Schmid (Plant Lipid Metabolism) taken with Applicant's admitted state of the art. For the following reasons, this rejection is respectfully traversed.

In rendering this rejection, the Examiner deems that "given the recognition of those of ordinary skill in the art of the value of transforming a plant, such as tobacco, with a CFA coding sequence to produce branched chain fatty acids in a plant and in seeds of the plant, one of ordinary skill in the art would have been motivated to modify the construct taught by Schmid to substitute a seed specific promoter, given that Schmid teaches that the accumulation of CPFA in seeds is desired, yet the CaMV 35 promoter is relatively weak during the latter part of seed development, and given that numerous seed specific promoters were known, as taught by Applicants' admitted state of the art, and the seed specific promoter would be a matter of choice, which would not confer patentable distinction on the claimed invention."

Applicants respectfully disagree with the Examiner's conclusions for the following reasons.

Schmid (Plant Lipid Metabolism) discloses that tobacco plants transformed with *Escherichia coli* cyclopropane fatty acid synthase under the control of the CaMv35S promoter produces dihydrosterculate. Schmid does not disclose that branched fatty acids are produced using cyclopropane synthase. Indeed, the fatty acid compositions of the leaf lipids from transformed tobacco are saturated and unsaturated palmitic acid (16:0, 16:3), saturated margaric acid (17:0), saturated and unsaturated stearic acid (18:0, 18:1, 18:2) and dihydrosterculate (DHS), as indicated in Figure 1 of this reference. These are not branched chain fatty acids.

In fact, the Examiner is referred to at least page 3 of the specification wherein it is stated that a ring in the aliphatic chain is not considered to be a branched fatty acid. Moreover, the nomenclature of branched chain fatty acids would require that the methyl, ethyl, propyl etc. group be designated on the aliphatic chain; i.e., 10-methyl 16:0. There is no such nomenclature of this nature disclosed in Schmid.

Applicant's admitted prior art does not render the present invention obvious since the mere knowledge of seed promoters which would be substituted for the CaMV 35S promoter of Schmid would still not lead the skilled artisan to the fact that branched chain fatty acids can be produced in plants using the construct described in Schmid. Moreover Schmid does not suggest how to modify the *Escherichia coli* cyclopropane fatty acids synthase such that branched chain fatty acids can be obtained in plants.

Lacking any suggestion of generating branched chain fatty acids in plants in Schmid, this rejection cannot be maintained.

Therefore, in view of the above, withdrawal of this rejection is respectfully requested.

From the foregoing, favorable action in the form of a Notice of Allowance is respectfully requested and such action is earnestly solicited.

Should any additional fee be deemed due, please charge such fee to our Deposit Account No. 22-0261, referencing docket number 31640-159397, and advise accordingly.

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